

# Drug Card Pre-Application Conference

Responses to questions posed at the Drug Card Pre-Application Conference & email

**NOTE:** Due to the extraordinary attendance at the conference, interest in this program, and resulting large number of questions received by us, we are answering questions on a rolling basis. If you do not see the answer to your question at this time, please check back frequently for updates. Also, some of the questions were similar to others, in which case we answered only one version of the question. Therefore, please carefully read through all of the questions and answers.

All questions received by us by December 31, 2003 will have answers posted by January 7, 2004.

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**Last Updated: December 30, 2003**

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## **Solicitation, Application Process & Timing (Endorsement)**

Can a prescription benefit manager (PBM) provide a discount card to Medicare recipients without being part of a managed care organization?

- A. PBM may operate its own drug card program as long as it meets all qualifications for Medicare approval. No partnership with a managed care organization is required for Medicare approval.

In order to be a provider of discount cards does a PBM have to be presently providing prescription cards to managed care organization?

- A. No.

Can an endorsed sponsor have multiple programs to accommodate private label customers? If not, do each of these customers need to submit a separate application for endorsement listing our organization as a subcontractor to meet the program requirements?

- A. An Applicant may submit applications to operate multiple approved programs; each with its own exclusive Medicare enrollment. The Applicant could then include private label customers' names and logos on the approved card's information and outreach materials, provided CMS approved such materials. However, in each case, the Applicant's name would be required to be displayed on all materials on which the Medicare name and/or logo appears since CMS is approving only the entities that submit the applications for approval, not the entities with which an Applicant subcontracts. Alternatively, private label customers wishing to offer an approved drug card without identifying the subcontractor managing the pharmacy benefit may each submit an application of their own, and identify the subcontractor managing the pharmacy benefit. In such instances, assuming a successful application, CMS will provide Medicare approval for the private label customer, whose drug card can be marketed with the Medicare name and logo, but without identifying the subcontractor.

Can a company submit more than one application? For example, assume we want to offer two discount card products, each at different costs to the Medicare member. Do we include both of these in one application, or do we submit two different applications? Can product variants (for example offering different network sizes, annual fees, lists of discounted drugs, etc.) be submitted under the same application?

- A. There is no limit to the number of drug card programs for which an organization may submit an application for Medicare endorsement. We encourage Applicants to submit only one application describing all the discount cards they may offer. However, Organizations may elect, for their administrative convenience, to submit a separate application for each program for which they are seeking approval.

Will organizations that participate in the Discount Card be at an advantage when the new Medicare drug benefit becomes effective in 2006?

- A. According to the authorizing legislation for both the Medicare-approved discount card drug program and the Part D (Medicare drug benefit), CMS will not consider

operation of an approved discount card as a qualification for participation as a prescription drug program under Part D. However, card sponsors offering an approved drug card whose performance results in significant customer satisfaction may find that that reputation provides a significant advantage in competing for enrollees once the Part D programs are open for enrollment.

If we want to sponsor more than one plan, can we submit another plan after the application is in?

- A. CMS will accept no applications for Medicare approval after January 30, 2004. However, entities that have already submitted an application prior to that date may submit an additional application (or an amendment to the submitted application) on or prior to January 30, 2004.

If the applicant is a 50-50 joint venture and uses a 100%-owned subsidiary of one of its owners (i.e., an affiliate) to meet an applicant requirement, must the applicant have a contract with the affiliate?

- A. In the scenario you describe, since a subsidiary is a separate business entity (e.g., is incorporated, has its own board of directors), the Applicant must provide evidence of a contract between the subsidiary and the Applicant if the subsidiary is to provide services related to the operation of the Applicant's approved drug card program.

Should the Notice of Intent be provided at the organization level or the plan level?

- A. The notice of intent should be provided by the organization seeking to offer the approved discount card program. With respect to Medicare managed care organizations, the notice should be provided by the managed care organization, not the managed care plan. Managed care organizations wishing to offer both an exclusive Medicare managed care plan drug card as well as general drug card available to all beneficiaries residing in the card program's service area need submit only one notice of intent to apply. Note that Medicare managed care organizations wishing to offer these two types of drug cards must submit two separate applications, one using the general solicitation and another using the Medicare managed care solicitation.

Do you anticipate there being any flexibility in the January 30, 2004 application deadline?

- A. To meet the six-month implementation deadline established by the Medicare-approved drug card program's authorizing statute, CMS has adopted an aggressive application review process. The January 30, 2004 deadline is crucial to ensuring that both card sponsors and CMS will be prepared to make this program fully operational (i.e., discounts and transitional assistance available to beneficiaries) by June 1, 2004.

To whom does the notice of intent get sent?

- A. Both the notice of intent and the CMS Connectivity Request are to be sent to Kim August. Please see our December 23, 2003 revisions to the solicitations for more details.

How many subcontracts may an Applicant use to meet the drug card program qualifications?

- A. There is no limit on the number of entities with which an Applicant may subcontract to meet the qualifications for Medicare approval of the ir discount drug card program. However, please note that in the case of the Covered Lives requirement, one subcontractor must meet the 1 million lives qualification by itself. For example, An Applicant may not use two subcontractors, each with 500,000 covered lives to meet the qualification. Similarly, an Applicant using a contractor to meet the three years experience requirement must use entities that by themselves each have three years experience. For example, an Applicant combining three entities with one-year experience each would not meet the experience qualification.

To be an endorsed sponsor for Medicare Part D in 2006, does the sponsor need to participate in the discount drug program in 2004 and 2005.

- A. No.

How do Medicare managed care organizations file a notice intent to apply with CMS?  
Medicare managed care organizations are to follow the same notice of intent to apply filing procedures as all other Applicants. Please refer to Section 2.1 of the updated version (December 23, 2003) of the Medicare managed care organization solicitation for clarified information on the filing of the notice of intent to apply.

Do those of us applying for special approval have to get out letters of intent in at the same time as everyone else?

- A. All organizations that may apply for Medicare approval (regardless of the type of program for which they are seeking approval – managed care, special approval, etc.) must submit on or before January 7, 2004 a notice of intent to submit an application (including the CMS Connectivity Request) to CMS. Applicants are asked to meet this deadline so that they can ensure that they can meet the connectivity qualifications of the program according to CMS’ announced approval schedule. Please note that a notice of intent does not obligate an organization to submit an application to CMS.

Do contracts for rebates or discounts with pharmaceutical manufacturers need to be reviewed or approved by CMS. Do templates of rebate contracts need to be submitted to CMS?

- A. Sponsors are required to attest to the existence of manufacturer contracts that are applicable to the drug card program, including identifying all such manufacturers. The minimum requirement is one contract. CMS requires sponsor applicants to provide contracts between the sponsor and subcontractor (if any) that negotiates pharmaceutical manufacturer rebates. CMS does not expect sponsors to provide manufacturer rebate contracts. Rather, sponsor applicants must provide a discussion about these contracts, as required by the application requirements in Section 3.2.2. of the general solicitation, including the sponsor must attest that such contract(s) exists and with what manufacturer(s).

### **Organizational Structure & Experience**

Can an approved card sponsor continue to operate its current (non-Medicare-approved) discount drug card for their Medigap members for no fee while operating a Medicare-approved drug discount card?

- A. Approved card sponsors may continue to offer their non-Medicare-approved drug cards.

## **Contracts**

As a card sponsor, can you establish additional subcontracting relationships throughout the term of the discount card program (e.g., organizations)? If so, does this require submission of an updated application to CMS?

- A. Card sponsors may establish additional subcontracting relationships during the term of their contract. Although this situation does not obligate the card sponsor to submit a new or amended application to CMS, the card sponsor is required to provide CMS with a notice of any change to its program that might affect its qualification for endorsement. Card sponsors are to provide such notice as soon as it occurs. With respect to a new subcontractor, when such subcontractor is responsible for an area that affects the sponsor's qualification for Medicare approval, CMS would expect to receive a description of the change (including how it will impact the card sponsor's program) as well as a copy of the executed contract.

Can a card sponsor close down before January 2006?

- A. Approved card sponsors will be required to sign a contract with CMS for a term beginning on May 3, 2004 and ending on the effective date of enrollment for the Part D program in 2006. A card sponsor may not terminate that contract unless it can demonstrate that CMS is not performing its obligations under the program or unless CMS mutually agrees to terminate the contract.

If a card sponsor uses a subcontractor who has subcontractors, does the card sponsor need to provide with the application (a) a single contract with the primary subcontractor, or (b) contracts with both primary and secondary subcontractors.

- A. Applicants need to provide only the contracts with primary, secondary or any other subcontractors for areas related to covered lives, years of experience, pharmacy network, discount and rebate negotiation, enrollment and transitional assistance eligibility, transitional assistance administration, grievance process operation, information and outreach materials development, and call center operation.

It appears there is an enrollment period in 2006 during which discounts must be offered. Please confirm that the actual term for which sponsor must operate the discount card program is May 2004 through the end of the Part D initial enrollment period in 2006 provided that beneficiaries enrolled in the endorsed card program have not migrated to the Part D benefit.

- A. It is correct that a Medicare endorsed sponsor must operate the discount card program is May 2004 through the end of the Part D initial enrollment period in 2006 provided that beneficiaries enrolled in the endorsed card program have not migrated to the Part D benefit. During 2006, beneficiaries may not switch cards and are not provided new transitional assistance funds. Sponsors may not charge an enrollment fee, sponsors must make negotiated prices available, and sponsors must administer on behalf of its enrollees any remaining balances in transitional assistance that rolled over from 2005.

### **Eligibility, Enrollment & Reconsiderations (Enrollment and Eligibility)**

CMS described group enrollment for Medicare managed care plans, where a member can opt out of a card that the managed care plan offers. Would it be possible to get a similar provision for Medigap carriers?

- A. Medigap plans may not group enroll under the drug card program. While we understand the predicament described, the statute contemplates beneficiaries making an active choice in: 1) selecting the card best serving their needs, 2) actively deciding to enroll in the card for discounts, and 3) actively deciding to apply for transitional assistance. Different from all other potential applicants, the statute contemplates special arrangements for Medicare coordinated care plans and Medicare cost contractors, if they decide to offer an exclusive card. Specifically, among other things, the statute requires that a beneficiary only join that plan's card. Therefore, the choice of another card is not an option for the beneficiary. In this circumstance we believe that group enrollment would not undermine the statutory intent of choice among cards, therefore we allow it, with the understanding that the beneficiary may decline. Medigap plans are not precluded from assisting their members in enrolling in a card they offer, provided that beneficiaries are informed that they have an option to join another card of their choice. CMS has provided for enrollment methods for the discount card (not including transitional assistance, which requires a signed form) that include telephone and Internet possibilities. It is our expectation that this flexibility will enable sponsor organizations to develop cost effective enrollment processes for their anticipated volume.

Will the income for purposes of determining eligibility for transitional assistance include social security income? Will the number of household members affect this amount? Is this amount total for the household or just the members on Medicare?

- A. The income threshold includes social security income. Income belonging to the applicant or, if the applicant is married, to both the applicant and spouse (whether the spouse receives Medicare or not) will be counted. No other household members' income will be counted.

Will disabled adults, under age 65, on Medicare be eligible for prescription drug discounts?

- A. Yes. The program is open to all eligible Medicare beneficiaries. All drug card applicants must meet the same eligibility criteria, namely, that they are eligible for or are enrolled in Medicare Part A or enrolled in Part B and are not receiving outpatient prescription drugs under their state's Medicaid program at the time of application for enrollment in the drug card.

Will all Medicare eligible recipients be eligible for the discount card or just those in a certain income bracket?

- A. All Medicare beneficiaries may apply for a discount card. Income is only a consideration for the Transitional Assistance portion of the program.

If a beneficiary enrolls in different programs in 2004 and 2005, how will the card sponsor who provided services for the member in 2004 be notified of the beneficiary's 2005 election?

- A. Elections made during the Annual Election Period (November 15, 2004 – December 31, 2004) will return an automatic disenrollment notice to the sponsor through the CMS enrollment exclusivity system.

What steps will CMS take when it discovers that a member has enrolled in more than one program? Please describe the notification CMS will make to the member and the program sponsors.

- A. Individuals may not be enrolled in more than one drug card sponsor at a time. Because all enrollments must be entered into the CMS enrollment exclusivity system, we expect that this scenario will not arise.

With respect to the annual enrollment fee that is to be collected by the program sponsor. Is CMS envisioning any specific process? (e.g. at enrollment, monthly, quarterly, etc.?)

We envision the annual enrollment fee being charged once annually. We have provided flexibility to sponsor organizations in the collection of this fee in that each organization may decide to either collect the fee with each enrollment, or bill each enrolled individual for such fee after enrollment. Remember, individuals who apply for Transitional Assistance must not be required to pay any enrollment fee. If the individual is determined eligible for Transitional Assistance, CMS will pay this fee to the sponsor on the beneficiary's behalf. If the individual is determined ineligible for Transitional Assistance s/he may elect to enroll in just the discount card (and pay the fee).

Will you make an enrollment form available in Spanish?

Yes, we will provide a translated application shortly after the English version is made available.

How will the beneficiaries apply for the discount cards?

The basic concept of the enrollment process is described in the regulation and the solicitation documents. Beneficiaries will complete an enrollment form, or other CMS approved method, and submit it to the discount card sponsor to whom they wish to belong. The sponsor will respond to each beneficiary with the appropriate determination and information.

The regulation says a sponsor cannot enroll a TA applicant in its drug card prior to an eligibility determination for TA, yet exclusive sponsors are permitted to group enroll its members, with application for TA deferred to later. Don't these rules conflict?

- A. We do not believe these rules conflict. The managed care group enrollment process includes that the required notification sent to all individuals prior to such enrollment will include information about transitional assistance, providing an opportunity to apply for it, as well as the opportunity to decline enrollment in the discount card. The statute creates special rules for members of managed care plans with exclusive drug cards and restricts such members to enrolling in only the exclusive cards. Other individuals (who are not in managed care plans offering exclusive cards) may decide that they wish to choose another discount card (for example, one with a lower enrollment fee) if they are not determined eligible for TA. Further, exclusive card sponsors may group enroll only for the drug card. If a beneficiary applies for transitional assistance then the same steps apply for sponsors of exclusive cards as for other sponsors, namely the beneficiary must provide a signed attestation of their income and other related eligibility requirements.

Can the dually eligible beneficiaries who participate in the Medicare Savings Programs -- (Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB) and Qualifying Individuals (QI) -- be group enrolled for TA?

No. They have to actively apply. However, if they do apply for TA -- QMBs, SLMBs and QIs are deemed to meet the income portion of the eligibility requirements.

Can a company charge a different enrollment fee for a Transitional Assistance plan than the fee charged for a regular discount card plan?

- A. No. The Medicare approved discount card program includes Transitional Assistance (TA); these are not separate plans. An individual who receives TA is an enrollee of the discount card. There is an annual enrollment fee for the program of up to \$30 charged by the sponsor, as it determines, to each individual for 2004 and 2005. Sponsors may not collect any enrollment fee from individuals applying for or enrolled in TA. The annual fee for discount card enrollees with TA will be paid by CMS.

Can a card sponsor charge an annual enrollment fee of \$30 for TA eligible beneficiaries, but at the same time waive the fee for "regular" discount card enrollees?

- A. No. This would not be permitted as any annual enrollment fee must be charged uniformly to all enrollees of a discount card program, within each state.

Has any thought been given to allowing those who apply for TA to get the discount card automatically if they are not eligible for TA?

- A. Yes, CMS weighed this option carefully. While such a process may seem a convenience to certain beneficiaries, for others it may impose an annual enrollment fee that the beneficiary would be required to pay. Further, due to the limits on when an individual may change cards, such a process could also inadvertently limit choice. To ensure that all individuals are aware of their options, the notice that is sent to those who applied for TA but were found ineligible informs them that they may choose to enroll in the discount card.

CMS said that if a member submits an enrollment on the last day of a month, with the enrollment process taking possibly several days after that to confirm eligibility and send an ID card, etc. to the enrollee, the sponsor would not be required to give retroactive discounts or TA payments. Is this accurate?

- A. Yes

Will a faxed signature be acceptable for Transitional Assistance enrollments?

- A. Yes. Beneficiaries applying for Transitional Assistance must complete and sign an enrollment form. Sponsors may accept this enrollment form in hard copy or by facsimile.

Will model language be provided for beneficiary reconsideration rights?

- A. Yes. CMS will provide model notification letters that include information to provide beneficiaries with their reconsideration rights.

Can a sponsor extend the periods described for sponsor disenrollment of a beneficiary who does not pay the annual enrollment fee, such as extend the 10 days following notification of delinquency to 30 or more days?

- A. Yes. The 10 days described in the solicitation is a minimum standard so a sponsor could not offer less. The period of time must be applied uniformly to all card program enrollees.

What are sponsors required to document when taking enrollments over the telephone or via the Internet?

- A. CMS expects sponsors interested in utilizing enrollment formats other than paper enrollment forms to develop processes that incorporate appropriate privacy, data protection and security measures. CMS security policies are available on the web at <http://www.cms.hhs.gov/it/security>.

An example of an acceptable process might be an individual's authorization to use a credit card to pay an annual enrollment fee as a method by which the sponsor authenticates the identity of the individual applying.

For enrollment via telephone, sponsors must document the elements included in the model enrollment form. Sponsors should also provide a process to identify the caller, which could again be an authorization to charge an enrollment fee to a credit card.

Do the notices of eligibility or ineligibility have to be sent in writing (hard-copy)?

- A. Yes. Models of notices will be provided.

Does the notice of ineligibility have to include the reason why an individual was found ineligible?

- A. Yes.

Can individuals found ineligible apply for reconsideration without documenting a change in the data used when they were found ineligible?

- A. When a beneficiary applies for the discount card program (with or without TA), and is found ineligible either because of answers to questions attested to on the enrollment form, or from the CMS systems verification process, he or she is entitled to apply for reconsideration of the eligibility result. The reconsideration process will involve the beneficiary's explaining why he or she disagrees with the result, including the submission of documentary evidence where applicable.

How will an individual having TRICARE or other coverage be determined?

- A. These questions, and others, will be on the enrollment form and the beneficiary will attest to the validity of the answers provided.

Is a beneficiary with M+C HMO coverage for outpatient drugs (not employer group health plans) eligible for transitional assistance?

- A. Yes. The legislation provides explicitly for that.

## **Drug Card Offering (Drugs, Rebates, and Discounts)**

What are the policies and procedures for manufacturers to charge discounts and rebates?

- A. Unless a manufacturer is a Medicare-endorsed sponsor, there are no policies and procedures specific to this program for manufacturers to follow, other than to be in compliance with any applicable State and Federal laws to the extent a manufacturer is in anyway associated with the drug card program. Also, manufacturers should be aware that covered discount card drugs under this program are exempt from Medicaid best price policy. If a manufacturer is applying to be a card sponsor, then the manufacturer is required either to apply discounts to the manufacturer's own prescription drugs (for example relative to the average whole sale price), and / or to obtain rebates, discounts, or other price concessions from other manufacturers on other covered discount card drugs. Also, like any other Medicare-endorsed sponsor, a manufacturer sponsor would be required to offer a negotiated price to beneficiaries (e.g., such as a manufacturer or pharmacy discount or other price concession) on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic group in Attachment 2 of the solicitation, and would be required to also offer a negotiated price for generic drugs in at least 55 percent of these same categories.

How often can a sponsor add or delete products from the program? Will there be allowances to change the formulary throughout the benefit period? If yes, what notification, if any, would be required?

- A. Importantly, any products offered initially in the application for Medicare-endorsement or added later must fit within the definition of "inside the scope of the endorsement", which is discussed in II.C.5 of the Medicare Prescription Drug Discount Card Interim Final Rule. Further, material modifications to a sponsor's application must be communicated to CMS as soon as they occur. Provided that these rules are followed, a sponsor may add products at any time. A sponsor will have an opportunity once a week to change its formulary, including adding and deleting covered discount card drugs offered for a negotiated price that is reported on the CMS price comparison website and / or the sponsor's electronic media, provided that the baseline formulary requirements continue to be met, and appropriate public disclaimers are associated with these changes (as will be discussed in the information and outreach guidelines; we do not require that beneficiaries to receive advance notice of changes). Other than changes from time to time in a card's covered discount card drugs offered for a negotiated price, we would expect product and service offerings related to the covered discount card drugs to remain stable across a calendar year. To the extent that changes to products and services are necessary, particularly a deletion, then we would expect to be notified, and the sponsor's information and outreach materials to be modified, in advance of implementing the change to avoid any beneficiary confusion. At no time is a sponsor's endorsed card program allowed to be out of compliance with the requirements for endorsement.

How shall the "rebate and discount levels to be shared" be defined? Is there a threshold level to qualify? Does a sponsor have to obtain a contract from all manufacturers? Do all

manufacturer and pharmacy rebates/discounts/other price concessions have to be passed through to the beneficiary at the point of sale?

- A. In response to the application requirement in Section 3.2.2. of the general application, which states, "Estimate the aggregate level of manufacturer rebates/discounts/other price concessions to be secured from drug manufacturers and the estimated total share that will be passed through to Medicare beneficiaries in the form of lower prices at the point of sale", an Applicant must provide a single estimated aggregate dollar amount of manufacturer rebates/discounts/other price concessions to be secured across all the sponsor's manufacturer contracts, and provide a single estimated percentage reflecting the portion of that dollar amount to be passed through to Medicare beneficiaries in the form of lower prices at the point of sale. A sponsor must have at least one manufacturer contract, and the reported estimated dollar amount and percentage share may not be zero; however, to be successful in attracting enrollees and maintaining their satisfaction under a sponsor's program, we believe a sponsor will need to negotiate manufacturer price concessions and pass through as much of the pharmacy and manufacturer price concessions as possible (e.g., after covering administrative costs), to provide competitive discounts at the point of sale.

Since a sponsor will receive any manufacturer rebates long after the point of sale, rather than pass through these rebates directly to the beneficiary, can the sponsor use the rebates to reduce enrollment fees?

- A. Sponsors are not required to charge an enrollment fee, but must charge the same fee to all beneficiaries within a state if they do charge a fee, and the fee may not change for the year. The expectation is that sponsors will estimate *anticipated* rebates and develop a negotiated price based in part on that estimate, and make future adjustments in negotiated prices -- up or down -- as necessary to accommodate mid-course accounting for actual rebates. (If prices increase within the year (except for the week of November 15) beyond the proportionate change in the AWP, then the sponsor must provide a notice and rationale as discussed in II.C.4.c of the drug card regulation.)

Can a card sponsor offer a generic only benefit?

- A. No. A card sponsor must provide a negotiated price on at least one drug in each of the 209 therapeutic categories provided in Attachment 2 of the general solicitation. Approximately half of these classes do not include Class A generics. For the categories that do include a Class A generic, the sponsor must provide a negotiated price on at least one generic in at least 95% of those categories; for such a category, a sponsor is not required to provide both a brand and generic drug for a negotiated price.

Can a card sponsor's program qualify for a Medicare endorsement without including in the negotiated prices some type of price concession obtained under contract from one or more manufacturer?

- A. No. Please refer to Section 3.2.2. of the general solicitation.

Can a sponsor incent the use of mail order pharmacy?

- A. Yes; however a sponsor may not require as part of the design of its drug program that enrollees use mail order. Also, any such incentives must still meet the program requirements. For example, a sponsor couldn't refund the enrollment fee to those who use mail order pharmacies.

When submitting participating pharmacies to CMS and providing pharmacy information to enrollees, can the list be abbreviated by saying, "all pharmacies in a certain chain (by name), are in our network"?

- A. In order to validate that a sponsor meets the pharmacy access standards, an applicant must provide the list of pharmacies as required in Section 3.3.2. of the general solicitation. In the print material provided to a beneficiary, the list must include the contracted pharmacies in the beneficiary's zip code or county. The list for a beneficiary may be abbreviated to indicate that all pharmacies in a certain chain (by name) in the beneficiary's area (zip code or county) are included in the card's network. Any contracted pharmacies that are in the beneficiary's area that are not represented by this type of abbreviation must be listed.

There are several regional pharmacy corporations that are interested in obtaining a Medicare endorsement for a discount card program. While these organizations have excellent penetration in their region, their regions are not consistent with state borders. Will waivers be considered for these groups?

- A. No, waivers on service area and pharmacy access will not be granted. Sections 1860D-31(e)(1)(B) and (h)(3) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 are very clear that a program must be available to all beneficiaries within a State that is included in the sponsor's card, and that the pharmacy access standards must apply in order for a program to be endorsed by Medicare.

## **Transitional Assistance**

Will SLMB/QMB individuals be required to fill out an application for transitional assistance if they are affiliated with an exclusive plan sponsor, or will they be deemed eligible (given that they should meet all of the requirements of eligibility – i.e., they can't be disqualified on the basis of having other drug coverage since there is an exception for Medicare Advantage members)?

- A. All transitional assistance enrollees must complete an enrollment form. Individuals that are SLMB/QMB or QI are deemed to meet the income requirement for transitional assistance only. All other eligibility factors apply.

Please confirm whether or not individuals with employer-sponsored M+C or MediGap coverage would qualify for transitional assistance.

- A. Yes. To be eligible, an individual may not have group health plan or individual coverage other than an M+C or Medigap plan. Please note, if the individual has both M+C and some other employer-sponsored health insurance offering coverage for prescription drugs, s/he would not be eligible.

A sponsor decides to require the \$30 enrollment fee up front. A beneficiary then applies for, and receives, transitional assistance. I'm assuming the MCO must refund the enrollment fee - is this a correct assumption? How long does the MCO have to refund the fee?

- A. A sponsor may only charge the enrollment fee upfront to those beneficiaries who are enrolling in the discount card only. Sponsors must not collect the fee from beneficiaries applying for transitional assistance. In the case where a beneficiary applies for and enrolls in the discount card only, paying the applicable fee, and then applies for transitional assistance at a future date, the sponsor must refund the fee paid by the beneficiary as it will collect the fee from CMS for transitional assistance enrollees. We have not established a time requirement for the processing of this refund, but expect sponsors to react promptly to this requirement. If our experience with the program necessitates the creation of a timeframe, we will do so and provide such guidance to sponsors.

If a beneficiary is enrolled in a non-exclusive card, will any unused TA follow the beneficiary into an exclusive card if the beneficiary joins a plan offering an exclusive card? How is this tracked?

- A. Yes, the transitional assistance will roll over any time a beneficiary changes cards during the annual enrollment period or a special enrollment period. The MCO offering the exclusive card in your scenario would be aware of the beneficiary's new enrollment in the plan and would be expected to provide to the beneficiary information about the exclusive card and how to enroll. At the time the beneficiary enrolls, the remaining balance on the card (which is provided to the enrollment system by the present sponsor at the time of disenrollment) would be rolled over to the exclusive card.

## **Marketing Materials & Review Process (Information and Outreach)**

Can a plan sponsor market two or more discount card programs with different application fees and program features?

- A. A sponsor can offer two programs with different enrollment fees and program features within the same service area.

Are there requirements of the sponsors to print membership cards that are consistent in look, or have CMS logo, or have consistent field layouts so the pharmacies recognize the cards and easily input the required fields

- A. The information and outreach guidelines will have specific requirements for membership card and the Medicare Mark. Card sponsors will be required to follow the NCPDP standards in developing their membership cards. Further guidance will be provided in the guidelines.

What are the requirements or expectations for communicating the transitional assistance balance remaining to the member at the point-of-sale? Do we need to amend our retail pharmacy contracts to obtain this result? Can the balance be made available electronically such as website or interactive voice system?

- A. Card Sponsors will be responsible for ensuring that contracted pharmacies are able to provide the balance of transitional assistance at the point of sale. Therefore Card Sponsors should specify in their pharmacy contracts that the balance of transitional assistance is a service that must be provided to the beneficiary at the pharmacy. The balance of transitional assistance must also be available through the Card Sponsor's customer service phone number.

Will we receive materials/guidelines to distribute with discount card applications to help seniors screen for transitional assistance so we can limit the number of transitional assistance applications

- A. The information and outreach guidelines will provide guidance on how to communicate transitional assistance and the requirements. CMS has developed model materials that will assist beneficiaries in understanding transitional assistance. This information will be communicated in the model Member Handbook and Annual Notice of Change. CMS has also developed standardized enrollment forms and eligibility determination letters that provide information on transitional assistance. Card Sponsors will also be responsible for providing this information in their summary of program features.

As a qualified Medicare approved drug discount card provider, will we have access to Medicare enrollees' names, address and phone numbers to mail our program literature and call them to solicit their enrollment in our program?

- A. CMS will not provide names and address to sponsors for their advertising campaigns.

## **Payment and Financials**

What is the process for reimbursing the M+COs for TA members? How will the claims system work?

- A. The M+COs will be paid the same way as the non-M+CO sponsors; through the Payment Management System. This method will allow daily payment. Other payment options involving the CMS Managed Care Payment system would have limited payments to monthly. We are not using a claims payment system.

If an individual misrepresents their eligibility for TA and CMS confirms this, but it is later determined that the individual is not eligible, who bears the liability for the funds expended on behalf of that individual?

- A. CMS is only going to verify eligibility once; upon receipt of an enrollment transaction from a sponsor. If CMS learns that the individual has misrepresented eligibility, the individual is liable for the funds expended on his/her behalf.

Will CMS systems accept a negative balance related to member's subsidies?

- A. Sponsors are required to submit the remaining subsidy balance monthly. When the member has exhausted their subsidy and the balance reaches zero, this monthly reporting stops. Deductions from the subsidy balance are to be based on finalized claims, so there should not be a negative balance to be reported. CMS systems will reject negative amounts. As we stated in the preamble to the final rule, "Endorsed sponsors must have a process for managing payment against an individual's transitional assistance cap to ensure that not more than the amount of transitional assistance available is provided to the individual."

Will CMS be sending beneficiaries statements of payments for TA funds (similar to statements that are sent for current {Part A payments})?

- A. CMS will not be sending the TA beneficiaries any statements regarding payments made on their behalf.

If a beneficiary gains TA on reconsideration, will the TA be pro-rated in 2005?

- A. The proration schedule is contained in the regulation; the member loses \$150 per quarter that he is not enrolled with a drug card sponsor. If the beneficiary is found to be eligible for TA after reconsideration, he is considered to have been enrolled as of the date of his initial application and is entitled to the subsidy amount allowable for that date.

## **Price Comparison Website**

If prices can vary by pharmacy contract, what price goes on the price compare?

- A. The price will reflect the maximum contracted negotiated price (including the dispensing fees) associated with the participating pharmacy for each drug offered through each respective drug card sponsor's program. This price will reflect the maximum price that a Medicare beneficiary would incur at the point of sale.

Will the slides from the conference on Price Comparison be shared on-line?

- A. Yes. The slides have been incorporated into the day 2 slide presentation, and they are available on the web at [www.cms.hhs.gov/discountdrugs](http://www.cms.hhs.gov/discountdrugs).

How often will a sponsor be able to submit price changes to CMS' Price Comparison website and how quickly will they be posted?

- A. Data for Price Comparison may be updated on a weekly basis. All card sponsors will submit their electronic drug pricing data files directly to CMS' contractor for Price Comparison, DestinationRx, Inc. All Data must be submitted by Midnight Pacific Time on Wednesday of each week. DestinationRx, Inc. will process and display the submitted data by 12:01 AM Eastern Time on Monday of each week.

### **Reporting and Performance Monitoring**

Will CMS further define the reporting requirements (such as the format and frequency)?

- A. Yes, as stated in the December 19<sup>th</sup> presentation on monitoring and reporting, we will provide this information via the CMS website at a later date.

How are you expecting sponsors to report rebates/discounts? Aggregate vs. average across all drugs and beneficiaries?

- A. This is described in Attachment 6 of the general solicitation. Further clarification, if needed, will be made available via our website.

What specific details must the grievance log consist of?

- A. The details are outlined in Attachment 6 of the general solicitation, please refer to it. Any further clarifications, as needed, will be made via our website.

**Systems, including that related to Eligibility & Enrollment, as well as Transaction Requirements, Infrastructure Requirements, Testing Plan, and "Go Live" Requirements (IT)**

During the presentation at the pre-application conference, it was stated that a systems survey was posted on the CMS website, but I cannot find the survey.

- A. The survey is titled the CMS Connectivity Questionnaire, which is now due January 7th with a sponsor's intent to bid. The CMS Connectivity Questionnaire is located at [www.cms.hhs.gov/discountdrugs](http://www.cms.hhs.gov/discountdrugs) under the related links categories for the solicitation. Please note the document is available as a MS Word document, which is found using the zipped link, or in PDF format.

Will Medicare cover the cost of the T1 lines for special cases?

- A. CMS's intent is to pay for one T1 line per sponsor if that sponsor does not currently have such connectivity to the CMS Data Center.

Can multiple subcontractors of a sponsor be electronically connected to CMS for eligibility/enrollment?

- A. CMS's intent is to pay for one T1 per sponsor. We are expecting one set of feeds per sponsor.

When will the system-training handout be available electronically?

- A. We expect to issue the file formats and the finalized business requirement supporting our system development activities by January 16. Test cases will be issued in mid February.

If a beneficiary is enrolled in a State Pharmacy Assistance Program, may they also receive benefits under the Discount card? If they qualify for the \$600 assistance and sign up for a Discount card, will they lose their benefits under the State program?

- A. Yes, beneficiaries may be enrolled under both. If a beneficiary qualifies for TA, it may be beneficial for them to participate in both so they receive \$600 in federal TA. CMS cannot say what the State discount program's enrollment rules may be in the future, but from our viewpoint, enrollment in both is permissible.

If a Medicare beneficiary who chooses to enroll in the Medicare-approved drug discount card program already was participating in a discount card program offered by a pharmaceutical company or other private entity (i.e., a card that is not Medicare-endorsed and pre-dated the Medicare discount card program), can the beneficiary continue to use the non-Medicare-endorsed card, as well as the Medicare-endorsed card?

- A. Yes. Enrollment in a Medicare-endorsed card would not preclude enrollment in any non-Medicare-endorsed card. It would however, preclude simultaneous enrollment in an endorsed Medicare card.

On what basis will the \$62 million in transitional coordination of benefits (COB) funding be distributed? Can the \$62 million be used for outreach, education, printing, mailing and so

forth? Can the funds be used for systems changes in an SPAP contractor's point-of-service system?

- A. The grant money to fund COB activities is part of the legislative provisions for the Part D benefit, not the drug card. CMS is analyzing that piece of the legislation and will provide guidance in the future.

## **States**

Can State Medicaid agencies require/mandate that card eligible recipients such as QMBs, SLMBs, QIs and other dual eligibles sign up for the card? Would it make a difference if the state allows them to disenroll voluntarily? Would it make a difference if the state paid their enrollment fee?

- A. State Medicaid programs are not permitted to establish additional eligibility requirements other than those provided for under Federal Medicaid law unless these conditions complement, rather than conflict with, Federal law and the State provides a rational purpose in support of imposing the additional conditions. If a State wishes to require that its Medicaid beneficiaries who are eligible for the Medicare-endorsed drug discount card program enroll in the program, we will review the State's proposal to see whether it meets these requirements.

## **HIPAA**

Does a subcontractor have to be HIPAA compliant?

- A. Subcontractors to a card sponsor -- which is a covered entity -- would be business associates to the sponsor for the purpose of operating the drug card program, and as such must be compliant with the provisions of HIPAA. Additionally, subcontractors may have other operating circumstances and relationships that would invoke HIPAA compliance that would not be modified by virtue of the subcontractor's relationship to the card sponsor. We recommend that sponsors and their subcontractors carefully evaluate the HIPAA provisions in order to understand and comply with them. We refer sponsors and their contractors to the following resources for more information: <http://hhs.gov/ocr/hipaa>, <http://www.cms.hhs.gov/hipaa/>, <http://www.aspe.hhs.gov/admsimp/index.shtml> .

Assuming a potential sponsor has access to beneficiary information as part of its Medicare Parts A and/ or B responsibilities, is it allowable to exchange that data to identify potential participants in the drug card / Part D programs?

- A. If the sponsor has access to beneficiaries' protected health information in its capacity as a business associate of another covered entity (for example, a carrier under contract with CMS), it may use or disclose such information to identify potential enrollees in its discount drug card program only if permitted to do so under its business associate contract with the covered entity. We note, however, that under the HIPAA Privacy Rule, the business associate contract generally may not authorize the business associate to use or disclose the protected health information in a manner that would violate the Privacy Rule if done by the covered entity. Since a covered entity may not use or disclose protected health information for the purposes of marketing a product or service separately provided by a third party, including its business associates, we believe it unlikely that a covered entity could authorize a business associate to use protected health information for the purpose of marketing the business associate's Medicare-approved drug discount card program.

### **Special Endorsement – Territories**

Isn't mail-order illegal in Puerto Rico?

- A. Based on our research, mail order is occurring in Puerto Rico, and that certain Puerto Rico laws have been held by the Federal Appeals Court of the First Circuit not to apply to mail-order pharmacies, see *National Pharmacies, Inc. v. Feliciano-De-Melici*, 221 F.3d 235 (1st Cir. 2000). We continue to review this issue.

### **Other**

How many of the 4.7 million people you estimate would be transitional assistance enrollees are in M+C?

- A. There are 7.3 million beneficiaries estimated to enroll in the drug card in 2004, with an estimated 4.7 million qualifying for transitional assistance and an estimated 2.6 million qualifying for the discount card only. Of the estimated 4.7 million transitional assistance enrollees, about 1.2 million are estimated to be in M+C. Of the estimated 2.6 million discount card only enrollees, the vast majority is assumed to be in Medicare fee-for-service. The major reason why the vast majority of the 2.6 million are assumed to be in traditional Medicare is that enrollment in the drug discount card only component is assumed to occur predominantly among beneficiaries without drug coverage, and many beneficiaries in M+C have drug coverage.